UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS

JODY LAGRONE	)	
	)	
Plaintiffs,	)	
	)	
v.	)	**Case No. 4:21-cv-4229**
	)	
ETHICON, Inc.; ETHICON, LLC; ETHICON, Ltd; and JOHNSON & JOHNSON CORPORATION	)	
	)	
Defendants.	)	

COMPLAINT AND JURY DEMAND

COMES NOW, Jody Lagrone, Plaintiff herein, complaining of Ethicon, Inc; Ethicon, LLC; Ethicon, Ltd; and Johnson & Johnson Corporation, Defendants herein, and for her cause of action Plaintiff alleges as follows:

I. PARTIES

A. Plaintiff

1. Plaintiff, Jody Lagrone, was at all times pertinent thereto a resident of the city of Houston, State of Texas, and a citizen of the State of Texas.

B. Defendants

2. Defendant Johnson & Johnson ("J&J") is a for-profit corporation organized under the laws of the State of New Jersey, with its worldwide headquarters located at One Johnson & Johnson Plaza, New Brunswick, New Jersey, a citizen of New Jersey. Defendant J& J is in the business of development, manufacture, testing, marketing, promotion, training, distribution, and sale of pelvic floor repair products. Defendant J&J is the citizen of the state of New Jersey. Defendant J&J may be served with process by serving its chief executive officer, Alex Gorsky, at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933.

3. Defendant Ethicon, Inc., is a wholly owned subsidiary of Defendant Johnson & Johnson located in Somerville, New Jersey, organized under the laws of the State of New Jersey with its principal place of business in New Jersey, a citizen of the State of New Jersey; and may be served with process by serving its registered agent for service, C T Corporation System at 1999 Bryan St., Suite 900, Dallas, Texas 75201-3136.

4. Defendant Ethicon, LLC, is a corporation organized under the laws of the State of New Jersey, is a wholly owned subsidiary of Defendant Johnson & Johnson Medical, Inc., with its principal place of business in San Lorenzo, Puerto Rico, a citizen of New Jersey and Puerto Rico, and may be served with process by serving its Chief Executive Officer, Willem Theodo Appelo, at 8 3 Road 183 km, San Lorenzo, PR 00754.

5. Defendant Ethicon, Ltd is a wholly owned subsidiary of Defendant Johnson & Johnson, organized under the laws of the State of New Jersey with its principal place of business in New Jersey, a citizen of the State of New Jersey; and may be served with process by serving its registered agent for service, C T Corporation System at 1999 Bryan St., Suite 900, Dallas, Texas 75201-3136.

6. At all times relevant herein, Defendants were engaged in the business of placing medical devices into the stream of commerce by designing, manufacturing, testing, training, marketing, promoting, packaging, labeling, and/or selling such devices, including Gynecare Prolift M total mesh product, which was implanted in Plaintiff's body.

7. Defendants had a legal duty to ensure the safety and effectiveness of their pelvic mesh products by conducting adequate and well controlled studies on their products prior to marketing. Defendants deliberately chose to manipulate the only studies that were conducted on their products and by doing so they provided doctors and patients with false and misleading information about the safety and effectiveness of their pelvic mesh products, including Gynecare

Prolift M total. Furthermore, Defendants made a conscious decision to forego performing studies and creating registries that would have provided doctors and patients in the United States with accurate information regarding the lack of proof of the safety and effectiveness of their pelvic mesh products.

II. JURISDICTION AND VENUE

8. The amount in controversy exceeds the sum of $75,000.

9. The civil action is between citizens of different states.

10. By reason of the foregoing circumstances, this Court has diversity jurisdiction over this lawsuit. 28 U.S.C. § 1332(a)(1).

11. This Court also has jurisdiction over this lawsuit and Defendants because Defendants maintained sufficient minimum contacts with the State of Texas such that the exercise of jurisdiction over Defendants would not offend traditional notions of fair play and substantial justice. Thus, the Court has general jurisdiction over Defendants. Further, Plaintiff's claims arose out of events occurring in the State of Texas. Thus, the Court also has specific jurisdiction over Defendants.

12. A substantial part of the events or omissions giving rise to Plaintiffs' claims occurred in this judicial district. Thus, venue over this lawsuit lays in this Judicial District. 28 U.S. C. § 1391(b)(2).

III. DEFENDANTS' PELVIC MESH PRODUCTS

13. In or about October, 2002, Defendants began to manufacture, market and sell a product known as Gynemesh, for the treatment of medical conditions in the female pelvis, primarily pelvic organ prolapse and stress urinary incontinence.

14. Gynemesh was derived from a product known as Prolene Mesh, which was used in the treatment of medical conditions in the female pelvis, primarily pelvic organ

prolapse and stress urinary incontinence. Prolene Mesh was derived from Defendants' Prolene mesh hernia product, and was and is utilized in the treatment of medical conditions in the female pelvis, primarily pelvic organ prolapse and stress urinary incontinence.

15. On or about January l, 2005, without seeking FDA clearance, the Defendants began to market and sell a product known as the Prolift System, for the treatment of medical conditions in the female pelvis, primarily pelvic organ prolapse and stress urinary incontinence. The ProliftSystem was and is offered as an anterior, posterior, or total repair system.

16. On or about May, 2008, the Defendants began to market and sell a product known as Prolift+M System, for the treatment of medical conditions in the female pelvis, primarily pelvic organ prolapse and stress urinary incontinence. The Prolift+M Total together with other Defendants' mesh products was and is offered as an anterior, posterior, or total repair system (hereinafter "Prolift mesh" or "Pelvic Mesh Product").

17. Defendants' Prolift mesh was designed, patented, manufactured, labeled, marketed, sold and distributed by the Defendants, at all times relevant herein.

IV. FACTUAL BACKGROUND

18. On or around July 20, 2009, Plaintiff was implanted with Gynecare Prolift M total mesh to treat her cystocele, rectocele, and urinary incontinence. The surgery was performed by Dr. David Scott Kent at Memorial Hermann Hospital in Katy, Texas. The Prolift mesh was used for anterior and posterior repair.

19. The Prolift mesh was identified as:
Description: Prolift M Total
Manufacturer: Gynecare
Manufacturer Number: pfrt02
Lot Number: 3270158
Expiration Date: 02/01/2012

20. Subsequent to the placement of the above mesh, Plaintiff suffered vaginal mesh

erosion from the above mesh.

21. On or around December 6, 2021, pieces of the defective Prolift mesh were surgically removed from Plaintiff's body. The surgery was performed by Dr. Lindo at Methodist Hospital. Unfortunately, Dr. Lindo was able to remove only three pieces of the mesh, the remainder of the Prolift mesh could not be removed without causing serious damage to Plaintiff's organs.

22. Surgical mesh products have been used to repair abdominal hernias since the 1950s. In the 1970s, gynecologists began using surgical mesh products designed for hernia repair for abdominal repair to surgically repair prolapsed organs. In the 1990s, gynecologists began using this surgical mesh for the surgical treatment of pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). Manufacturers, including Defendants, began to modify the mesh used in hernia repair to be used as products specifically intended to correct POP an SUI. Today, defendants sell pelvic mesh "kits" which can include not only the surgical mesh, but also tissue fixation anchors and insertion tools. The Products manufactured by Defendants are considered Class II medical devices.

23. Defendants' Prolift mesh products are targeted for women who suffer from pelvic organ prolapse and stress urinary incontinence as a result of the weakening or damage caused to the walls of the vagina. These products are specifically promoted to physicians and patients as an innovative, minimally invasive procedure with minimal local tissue reactions, minimal tissue trauma and minimal pain while correcting vaginal prolapse, stress urinary incontinence, pelvic organ prolapse and/or rectocele.

24. Moreover, these Prolift mesh products contain polypropylene mesh. Despite claims that this material is inert, the scientific evidence shows that this mesh material is biologically incompatible with human tissue and promotes an immune response in a large subset

of the population receiving Defendants' Prolift mesh products. This immune response promotes degradation of the polypropylene mesh, as well as the pelvic tissue, and can contribute to the formation of severe adverse reactions to the mesh.

25. At various times, Defendants sought and obtained Food and Drug Administration ("FDA") clearance to market the pelvic mesh products under Section 510(k) of the Medical Device Amendment. Section 510(k) allows marketing of medical devices if the device is deemed substantially equivalent to other legally marketed predicate devices marketed prior to May 28, 1976. This clearance process did not require Defendants to prove the safety or efficacy of the pelvic mesh and, thus, a formal review of the safety and efficacy of the pelvic mesh was never conducted with regard to the Products. In the case of the Prolift mesh product, Defendants marketed and sold the product for human implantation for over two years without the necessary clearance under Section 510(k)

26. Defendants' Prolift mesh has been and continues to be marketed to the medical community and directly to patients as safe, effective, reliable, medical device; implanted by safe and effective, minimally invasive surgical techniques for the treatment of medical conditions, primarily vaginal vault prolapse, stress urinary incontinence, pelvic organ prolapse and/or rectocele, and as safer and more effective as compared to the traditional products and procedures for treatment, and other competing Pelvic Mesh Products.

27. The Defendants have marketed and sold the Prolift mesh to the medical community at large and directly to patients, including Plaintiff, through carefully planned, multifaceted marketing campaigns and strategies. These campaigns and strategies include, but are not limited to, aggressive marketing to health care providers at medical conferences, hospitals, private offices, and include the provision of valuable cash and non-cash benefits to health care providers. Defendants also utilized documents, patient brochures, and websites,

offering exaggerated and misleading expectations as to the safety and utility of the Prolift mesh. Defendants further engaged in direct-to-consumer marketing specifically designed to drive consumers to seek out this product for implantation into their bodies.

28. At all times relevant to this action, Defendants intentionally, recklessly and/or negligently concealed, suppressed, omitted, and misrepresented the risks, dangers, defects, and disadvantages of the Prolift mesh and advertised, promoted, marketed, sold and distributed the Prolift mesh as a safe medical device when, in fact, Defendants knew that the Prolift mesh was not safe for its intended purposes and that the Prolift mesh would cause, and did cause, serious medical problems and injuries.

29. For example, Defendants described in its Patient Brochures, Instructions for Use, and other marketing materials, that the known complications for its Prolift mesh were consistent with any surgical procedure of an implantable medical device and described such occurrences as "rare" and "small" when in fact Defendants knew or should have known that the complications were not "rare nor small" but common, permanent, and debilitating.

30. Contrary to Defendants' representations and marketing to the medical community and to the patients themselves, the Defendants' Prolift mesh has high malfunction, failure, injury, and complication rates, fail to perform as intended, require frequent and often debilitating re-operations, and have caused severe and irreversible injuries, conditions, and damage to a significant number of women, including the Plaintiff, making Prolift mesh defective under the law. The Prolift mesh's defects include, but are not limited to, the following:

a. the use of polypropylene material in the mesh itself and the immune reaction that results, causing adverse reactions and injuries;

b. specifically in the Prolift + M, the use of polypropylene in combination with monocryl, a partially dissolvable mesh that increases the immune reaction and inflammatory response;

c. the design of the Prolift mesh to be inserted transvaginally into an area of the body with high levels of bacteria, yeast, and fungus that adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

d. the procedure itself, which is a part of the Prolift mesh, requires to the physician to insert the device "blindly," resulting in nerve damage and damage to other internal organs;

e. biomechanical issues with the design of the mesh that create strong amounts of friction between the mesh and the underlying tissue that subsequently cause that tissue to degrade resulting in injury;

f. the lack of porosity in the mesh resulting in the formation of a scar plate that prohibits tissue in-growth, resulting in mesh contraction, nerve damage, pain, and erosion of the mesh into other organs, and failure of the device;

g. the use and design of anchors in the Prolift mesh which when placed correctly are likely to pass through and injure major nerve routes in the pelvic region;

h. degradation of the mesh itself over time which causes the internal tissue to degrade resulting in injury;

i. particle loss and or "shedding" of the mesh both during implantation and following implantation that results in additional undesirable complications including an increased inflammatory response and a migration of those particles resulting in injury.

j. the welding and heating of the mesh itself during production which creates a toxic substance that contributes to the degradation of the mesh and host tissue alike;

k. the design of trocars, as devices to insert the Prolift mesh into the vagina, are defective because the device requires tissue penetration in nerve rich environments which results frequently in the destruction of nerve endings causing pain and other injuries;

l. the propensity of the mesh for "creep", or to gradually elongate and deform when subject to prolonged tension inside the body;

m. the propensity of the mesh to contract, retract, and/or shrink inside the body;

n. the inelasticity of the mesh, causing them to be improperly matted to the delicate and sensitive areas of the vagina and pelvis where they are implanted, and causing pain upon normal daily activities that involve movement in the pelvic region (e.g., intercourse, defecation, walking); and

o. the creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanting according to the manufacturer's instructions.

31. Upon information and belief, the Defendants have consistently underreported and withheld information about the propensity of Defendants' Prolift mesh to fail and cause injury and complications, and have misrepresented the efficacy and safety of the Prolift mesh, through various means and media, actively and intentionally misleading the FDA, the medical community, patients, and the public at large.

32. Defendants have further deliberately chosen to forego the conduct of studies and registries to avoid reporting obligations that would be mandated under the federal regulations upon receipt of adverse event information.

33. Despite the chronic underreporting of adverse events associated with the Defendants' Prolift mesh, the underreporting of events associated with similarly designed competitor products, and Defendants' deliberately avoiding the conduct of studies and registries to avoid the reporting of adverse events, eventually enough complaints were recorded for the FDA to issue a public health notification regarding the dangers of these devices.

34. On October 20, 2008, the Food and Drug Administration ("FDA") issued a Public Health Notification that described over 1,000 complaints (otherwise known as "adverse events") that had been reported over a three-year period relating to Pelvic Mesh Products. Although the FDA notice did not identify the transvaginal mesh manufacturers by name, a review of the FDA's MAUDE database indicates that the Defendants are one of the manufacturers of the Pelvic Mesh Product that is the subject of the notification.

35. On July 13, 2011, the FDA issued a Safety Communication: "UPDATE on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse." Therein, the FDA advised that it had conducted an updated analysis of adverse events reported to the FDA and complications reported in the scientific literature and concluded

that surgical mesh used in transvaginal repair of Pelvic Organ Prolapse was an area of "continuing serious concern." (emphasis added) The FDA concluded that serious complications associated with surgical mesh for transvaginal repair of Pelvic Organ Prolapse, were “not rare.” These serious complications include, but are not limited to neuromuscular problems, vaginal scarring/ shrinkage and emotional problems. Many of the serious complications required medical and surgical treatment and hospitalization.

36. The FDA concluded in its Safety Communication that it was not clear that transvaginal repair of Pelvic Organ Prolapse with mesh or repair of SUI with mesh kits are more effective than traditional non mesh repair of pelvic organ prolapse. Further, the FDA conducted a systematic review of the published scientific literature from 1996-2011 and concluded that based thereon, that transvaginal pelvic organ prolapse repair with mesh "does not improve symptomatic results or quality of life over traditional non mesh repair." The FDA concluded that "a mesh procedure may put the patient at risk for requiring additional surgery or for the development of new complications. Removal of the mesh due to mesh complications may involve multiple surgeries and significantly impair the patient's quality of life. Complete removal of mesh may not be possible."

37. The information contained in the FDA's Public Health Notification of October 2008 and the FDA Safety Communication of July 13 2011, was known or knowable to Defendants and was not disclosed in oral or written communications, direct to consumer advertising in the form of patient brochures, instructions for use, or labeling.

38. In fact, at the time Defendants began marketing each of its Pelvic Mesh Products, Defendants were aware that its Pelvic Mesh Products were associated with each and every one of the adverse events communicated by the FDA in its July 13, 2011 Safety Communication.

39. In a December 2011 Joint Committee Opinion, the American College of

Obstetricians and Gynecologists ("ACOG") and the American Urogynecologic Society ("AUGS") also identified physical and mechanical changes to the mesh inside the body as a serious complication associated with vaginal mesh, stating: There are increasing reports of vaginal pain associated with changes that can occur with mesh (contraction, retraction, or shrinkage) that result in taut sections of mesh . . . Some of these women will require surgical intervention to correct the condition, and some of the pain appears to be intractable.

40. Defendants knew or should have known about the Products' risks and complications identified in the FDA Safety Communication and the ACOG/AUGS Joint Committee Opinion.

41. Defendants also knew or should have known that: (1) some of the predicate products for the Pelvic Mesh Products had high failure and complication rates, resulting in the recall of some of these predicate devices (including a medical device known as Protogen device); (2) that there were and are differences between the Defendants' Pelvic Mesh Products and some or all of the predicate products, rendering them unsuitable for designation as predicate products; (3) that significant differences exist and existed between the Pelvic Mesh Products and their predecessor and predicate products, such that the disclosures to the FDA were and are incomplete and misleading; and (4) that the Pelvic Mesh Products were and are causing numerous patients severe injuries and complications.

42. The Defendants suppressed this information and failed to accurately and completely disseminate or share this and other critical information with the FDA, health care providers, and the patients. As a result, the Defendants actively and intentionally misled and continue to mislead the public, including the medical community, health care providers and patients, into believing that the Prolift mesh and the procedures for implantation were and are

safe and effective, leading to the prescription for and implantation of the Prolift mesh into Plaintiff.

43. Defendants' Prolift mesh product is also defective due to Defendants' failure to adequately warn or instruct the Plaintiff and/or her health care providers of risks and complications including, but not limited to, the following:

a. the Prolift mesh's propensities to contract, retract, and/or shrink inside the body;

b. the Prolift mesh's propensities for degradation, fragmentation and/or creep;

c. the Prolift mesh's inelasticity preventing proper mating with the pelvic floor and vaginal region;

d. the Prolift mesh's lack of porosity in preventing proper mating with the pelvic floor and vaginal region.

e. the rate and manner of mesh erosion or extrusion;

f. the risk of chronic inflammation resulting from the Prolift mesh;

g. the risk of chronic infections resulting from the Prolift mesh;

h. the risk of permanent vaginal or pelvic scarring as a result of the Prolift mesh;

i. the risk of permanent vaginal shorting as a result of the Prolift mesh;

j. the risk of recurrent, intractable pelvic pain and other pain resulting from the Prolift mesh;

k. the need for corrective or revision surgery to adjust or remove the Prolift mesh;

l. the severity of complications that could arise as a result of implantation of the Prolift mesh;

m. the hazards associated with the Prolift mesh;

n. the Prolift mesh's defects described herein;

o. treatment of pelvic organ prolapse and stress urinary incontinence with the Prolift mesh is no more effective than feasible available alternatives;

p. treatment of pelvic organ prolapse and stress urinary incontinence with the Prolift mesh exposes patients to greater risk than feasible available alternatives;

q. treatment of pelvic organ prolapse and stress urinary incontinence with the Prolift mesh makes future surgical repair more difficult than feasible available alternatives;

r. use of the Prolift mesh puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

s. removal of the Prolift mesh due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and

t. complete removal of the Prolift mesh may not be possible and may not result in complete resolution of the complications, including pain; and

u. the fact that neither pelvic organ prolapse, nor stress urinary incontinence, are life threatening conditions, and that other options, including nonsurgical options, were available and superior alternatives to the use of the Prolift mesh.

44. Defendants also failed to perform or rely on proper and adequate testing and research in order to determine and evaluate the risks and benefits of their Prolift mesh.

45. Defendants failed to design and establish a safe, effective procedure for removal of the Prolift mesh. Therefore, in the event of a failure, injury, or complications, it is impossible to easily and safely remove the Prolift mesh.

46. Feasible and suitable alternative designs as well as suitable alternative procedures and instruments for implantation have existed at all times relevant as compared to the Defendants' Prolift mesh. Safer alternative designs include, but may not be limited to:

a. the use of polyethylene material in the mesh itself and the immune reaction that results, causing adverse reactions and injuries;

b. a greater level of porosity in the mesh

c. not welding and heating the mesh itself during production so as not to creates a toxic substance that contributes to the degradation of the mesh and host tissue alike;

d. Mesh with greater elasticity

47. The Prolift mesh was at all times utilized and implanted in a manner foreseeable to the Defendants, as Defendants generated the instructions for use, created the procedures for implanting the device, and trained the implanting physicians.

48. Furthermore, the Defendants provided incomplete, insufficient, and misleading training and information to physicians, in order to increase the number of physicians utilizing the Prolift mesh, and thus increase the sales of the Prolift mesh, and also leading to the dissemination of inadequate and misleading information to patients, including Plaintiff.

49. The Prolift mesh implanted into the Plaintiff was in the same or substantially similar condition as it was when it left the possession of Defendants, and in the condition directed by and expected by the Defendants.

50. Plaintiff and Plaintiff's physicians foreseeably used and implanted the Prolift mesh, and did not misuse or alter it in an unforeseeable manner.

51. The injuries, conditions, and complications suffered by women who have been implanted with Defendants' Pelvic Mesh Products include, but are not limited to, mesh erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia (pain during sexual intercourse), inability to engage in sexual relations, urinary problems, inability to void, blood loss, neuropathic and other acute and chronic nerve damage and pain, pudendal nerve damage, shortening of the vagina, pelvic floor damage, chronic pelvic pain, urinary and fecal incontinence, prolapse of organs, and in many cases the women have been forced to undergo intensive medical treatment, including but not limited to, operations to locate and remove mesh, operations to attempt to repair pelvic organs, tissue, and nerve damage, the use of pain control and other medications, injections into various areas of the pelvis, spine, and the vagina, and operations to remove portions of the female genitalia.

52. The medical and scientific literature studying the effects of polypropylene pelvic mesh, like Defendants' Prolift mesh, have examined each of these injuries, conditions, and complications and determined that they are in fact casually related to the mesh itself and do not often implicate errors related to the implantation of the devices.

53. Defendants misrepresented to the medical and healthcare community, Plaintiff, the FDA, and the public that the Prolift mesh had been tested and was found to be safe and effective for the purposes of treating incontinence and/or prolapse.

54. In the case of the Prolift device, Defendants misrepresented to the Plaintiff, to the Plaintiff's physicians, and to the medical community at large, that such product had been properly cleared for marketing by the FDA when in fact no such clearance had been sought or obtained.

55. These representations were made by Defendants with the intent of inducing the medical community, Plaintiff, and the public, to recommend, prescribe, dispense, and purchase the Prolift mesh for use as a means of treatment for stress urinary incontinence and/or prolapse, all of which evinced an indifference to the health, safety, and welfare of Plaintiff.

56. Defendants failed to undertake their duties to properly know the qualities of their Prolift mesh and in representations to Plaintiff and/or to Plaintiff's healthcare providers, and concealed and intentionally omitted the following material information:

a. That the Prolift mesh was not as safe as other products and procedures available to treat incontinence and/or prolapse;

b. That the Prolift mesh was not as effective as other products and procedures available to treat incontinence and/or prolapse;

c. That the risk of adverse events with the Prolift mesh was higher than with other products and procedures available to treat incontinence and/or prolapse;

d. That the risk of adverse events with the Prolift mesh was not adequately tested and was known by Defendants;

e. That the limited clinical testing revealed the Prolift mesh had a higher risk of adverse effects, in addition to, and above and beyond those associated with other products and procedures available to treat incontinence and/or prolapse;

f. That Defendants failed to follow up on the adverse results from clinical studies and buried and/or misrepresented those findings;

g. That Defendants were aware of dangers in the Prolift mesh in addition to and above and beyond those associated with other products and procedures available to treat incontinence and/or prolapse;

h. That the Prolift mesh was dangerous and caused adverse side effects, including but not limited to higher incidence of erosion and failure, at a much more significant rate than other products and procedures available to treat incontinence and/or prolapse;

i. That patients needed to be monitored more regularly than usual while using the Prolift mesh and that in the event the Prolift mesh needed to be removed that the procedures to remove it had a very high failure rate and/or needed to be performed repeatedly;

j. That the Prolift mesh was manufactured negligently;

k. That the Prolift mesh was manufactured defectively; and

l. That the Prolift mesh was designed negligently, and designed defectively.

57. Defendants were under a duty to disclose to Plaintiff and Plaintiff's physicians, the defective nature of the Prolift mesh, including, but not limited to, the heightened risks of erosion, failure and permanent injury.

58. Defendants had sole access to material facts concerning the defective nature of the Prolift mesh and their propensity to cause serious and dangerous side effects and hence, cause dangerous injuries and damage to persons who used the Prolift mesh, such as the Plaintiff.

59. Defendants' concealment and omissions of material fact concerning the safety of the Prolift mesh were made to cause the Plaintiff, the Plaintiff's physicians and healthcare providers to purchase, prescribe, and/or dispense the Prolift mesh; and/or to mislead Plaintiff and Plaintiff's physicians into reliance and cause Plaintiff to have the Prolift mesh implanted into her body.

60. At the time these representations were made by Defendants, and at the time Plaintiff used the Prolift mesh, Plaintiff was unaware of the falsehood of these representations, and reasonably believed them to be true.

61. Defendants knew and had reason to know that the Prolift mesh could and would cause severe and grievous personal injury to Plaintiff, and that the Prolift mesh was inherently dangerous in a manner that exceeded any purported, inaccurate, or otherwise downplayed warnings.

62. In reliance upon these false representations, Plaintiff was induced to, and did use the Prolift mesh, thereby sustaining severe and permanent personal injuries and damages. Defendants knew or had reason to know that Plaintiff and Plaintiff's physicians and other healthcare providers had no way to determine the truth behind Defendants' concealment and omissions, and that these included material omissions of facts surrounding the use of the Prolift mesh, as described in detail herein.

63. As a result of Defendants' research and testing or lack thereof, Defendants distributed false information, including but not limited to assuring Plaintiff and Plaintiff's healthcare providers and physicians, that the Prolift mesh was safe for use or safer than other products and/or procedures available and on the market. Further, Defendants misrepresented to the Plaintiff and to the Plaintiff's physicians that the Prolift mesh was more effective than other means of treatment for these conditions for which it was implanted. As a result of Defendants' research and testing, or lack thereof, Defendants intentionally omitted, concealed and suppressed certain results of testing and research to healthcare professionals and Plaintiff.

64. Defendants had a duty when disseminating information to the public to disseminate truthful information and a parallel duty not to deceive the Plaintiff, Plaintiff's healthcare providers, and the FDA.

65. The information distributed to the public, the medical community, the FDA, and Plaintiff by Defendants included, but was not limited to, reports, press releases, advertising campaigns, television commercials, print advertisements, billboards and other commercial media containing material representations, which were false and misleading, and contained omissions and concealment of the truth about the dangers of the use of the Prolift mesh.

66. Defendants intentionally made material misrepresentations to the medical community and public, including Plaintiff, regarding the safety of the Prolift mesh specifically, that the Prolift mesh did not have dangerous and/or serious adverse health safety concerns, and that the Prolift mesh was as safe as other means of treating vaginal vault prolapse, stress urinary incontinence, pelvic organ prolapse or rectocele.

67. Defendants intentionally failed to inform the public, including Plaintiff, of the high failure rate including erosion, the difficulty of removing the mesh, and the risk of permanent injury.

68. Defendants chose to over-promote the safety, efficacy and benefits of the Prolift mesh instead.

69. Defendants' intent and purpose in making these misrepresentations was to deceive the public, the medical community, and Plaintiff; to gain the confidence of the public, the medical community, and Plaintiff; to falsely assure them of the quality and fitness for use of the Prolift mesh; and induce Plaintiff, the public and the medical community to request, recommend, prescribe, dispense, purchase, and continue to use the Prolift mesh.

70. Upon information and belief, Defendants made claims and representations in its documents submitted to the FDA and its reports to the public and to healthcare professionals and in advertisements that the Prolift mesh did not present serious health risks.

71. These representations, and others made by Defendants, were false when made and/or were made with the pretense of actual knowledge when such knowledge did not actually exist, and were made recklessly and without regard to the true facts.

72. These representations, and others made by Defendants, were made with the intention of deceiving the Plaintiff, Plaintiff's healthcare professionals and other members of the healthcare community, and were made in order to induce the Plaintiff, and Plaintiff's healthcare professionals, to rely on misrepresentations, and caused the Plaintiff to purchase, rely, use, and request the Prolift mesh, and caused her healthcare professionals to dispense, recommend, or prescribe the Prolift mesh.

73. Defendants recklessly and/or intentionally falsely represented the dangerous and serious health and safety concerns inherent in the use of the Prolift mesh to the public at large, for the purpose of influencing the sales of Prolift mesh known to be dangerous and defective, and/or not as safe as other alternatives. Defendants utilized direct-to consumer advertising to market, promote, and advertise the Prolift mesh.

74. At the time the representations were made, Plaintiff and Plaintiff's healthcare providers did not know the truth about the dangers and serious health and/or safety risks inherent in the use of the Prolift mesh. Plaintiff did not discover the true facts about the dangers and serious health and/or safety risks, nor did Plaintiff discover the false representations of Defendants, nor would Plaintiff with reasonable diligence have discovered the true facts or Defendants' misrepresentations.

75. Had the Plaintiff known the true facts about the dangers and serious health and/or safety risks of the Prolift mesh, or in the case of the Prolift System, that the Defendants had not sought nor obtained FDA clearance for the product, the Plaintiff would not have purchased, used, or relied on Defendants' Prolift mesh.

76. At all times relevant herein, the Prolift mesh was widely advertised and promoted by the Defendants as a safe and effective treatment for vaginal vault prolapse, stress urinary incontinence, pelvic organ prolapse or rectocele. Defendants minimized the risks posed to rectocele and vaginal prolapse patients with implantation of the Prolift mesh.

77. At all times relevant to this action, Defendants knew that the Prolift mesh was not safe for the patients for whom it was prescribed and implanted, because the mesh eroded and otherwise malfunctioned, and therefore failed to operate in a safe and continuous manner, causing injuries including, but not limited to, erosion, extrusion, infection, sepsis, chronic foreign body invasion, dense adhesions and worsening dyspareunia. Removal of eroded or infected mesh brings a high rate of life-threatening complications including permanent disfigurement and hemorrhage. Removal can require multiple surgical interventions in the operating theater for complete removal and results in scarring on fragile compromised pelvic tissue and muscles.

78. Defendants failed to design and establish a safe, effective procedure for removal of the Prolift mesh, or to determine if a safe, effective procedure for removal of the Prolift mesh exists.

79. At all relevant times herein, Defendants continued to promote Prolift mesh as safe and effective even when no clinical trials had been done supporting long or short term efficacy.

80. In doing so the Defendants concealed the known risks and failed to warn of known or scientifically knowable dangers and risks associated with the Prolift mesh for treatment of vaginal vault prolapse, stress urinary incontinence, pelvic organ prolapse or rectocele.

81. At all relevant times herein, Defendants failed to provide sufficient warnings and instructions that would have put the Plaintiff on notice of the dangers and adverse effects caused by implantation of the Prolift mesh including, but not limited to, mesh erosion, dense adhesions,

worsening dyspareunia, chronic pain, infection, sepsis, permanent disfigurement and multiple surgeries for mesh removal.

82. The Prolift mesh as designed, manufactured, distributed sold and/or supplied by Defendants was defective as marketed due to inadequate warnings, instructions, labeling and/or inadequate testing in the presence of Defendants' knowledge of lack of pelvic health safety.

83. At all times herein mentioned, the employees, agents, officers and/or directors of the Defendants named herein participated in, authorized and/or directed the production and promotion of the aforementioned Prolift mesh when they knew of the hazards and dangerous propensities of said Prolift mesh, and thereby actively participated in the tortuous conduct that resulted in the injuries suffered by Plaintiffs.

V. FRAUDULENT CONCEALMENT

84. Defendants' failure to document or follow up on the known defects in its product, and concealment of known defects, constitutes fraudulent concealment that equitably tolls applicable statutes of limitation.

85. Defendants are estopped from relying on the statute of limitations defense because Defendants actively concealed the defects, suppressing reports, failing to follow through on FDA notification requirements, and failing to disclose known defects to physicians. Instead of revealing the defects, Defendants continued to represent its Prolift mesh as safe for their intended use.

86. Defendants are and were under a continuing duty to disclose the true character, quality, and nature of risks and dangers associated with their Prolift mesh. Because of Defendants' concealment of the true character, quality and nature of their Prolift mesh, Defendants are estopped from relying on any statute of limitations defense.

87. Defendants furthered this fraudulent concealment through a continued and systematic failure to disclose information to Plaintiff, physicians, and the public.

88. Defendants' acts before, during and/or after the act causing Plaintiff's injuries prevented Plaintiff from discovering the injury or cause thereof.

89. Defendants' conduct, as described in the preceding paragraphs, amounts to conduct purposely committed, which Defendants must have realized was dangerous, heedless and reckless, without regard to the consequences or the rights and safety of Plaintiff.

90. Defendants' conduct, as described in the preceding paragraphs, also amounts to a continuing tort, and continues up through and including the date of the filing of Plaintiff's Complaint.

VI. CAUSES OF ACTION

COUNT I: NEGLIGENCE

91. Paragraphs 1-90 of the Complaint are hereby incorporated by reference as if fully set forth herein.

92. Defendants had a duty to individuals, including Plaintiff, to exercise reasonable and ordinary care in the manufacture, design, labeling, packaging, testing, instruction, warning, selling, marketing, distribution, and training related to its Prolift mesh.

93. Defendants breached their duty of care and were negligent as described herein in the design, manufacture, labeling, warning, instruction, training, selling, marketing, and distribution of the Prolift mesh in one or more of the following respects:

a. Failing to design the Prolift mesh so as to avoid an unreasonable risk of harm to Plaintiff in whom the Prolift mesh was implanted;

b. Failing to manufacture the Prolift mesh so as to avoid an unreasonable risk of harm to Plaintiff in whom Prolift mesh was implanted;

c. Failing to use reasonable care in the testing of the Prolift mesh so as to avoid an unreasonable risk of harm to Plaintiff in whom the Prolift mesh was implanted;

d. Failing to use reasonable care in inspecting the Prolift mesh so as to avoid unreasonable risk of harm to Plaintiff in whom the Prolift mesh was implanted;

e. Failing to use reasonable care in training its employees and health care providers related to the use of the Prolift mesh so as to avoid unreasonable risk of harm to Plaintiff in whom the Prolift mesh was implanted;

f. Failing to use reasonable care in instructing and/or warning health care providers, the FDA and the public as set forth herein of risks associated with the Prolift mesh, so as to avoid unreasonable risk of harm to Plaintiff in whom the Prolift mesh was implanted;

g. Failing to use reasonable care in marketing and promoting the Prolift mesh, so as to avoid unreasonable risk of harm to Plaintiff in whom the Prolift mesh was implanted;

h. In negligently and carelessly promoting the use of the Prolift mesh to physicians who had not received sufficient training to master the techniques necessary for implantation of the device into the Plaintiff;

i. Otherwise negligently or carelessly designing, manufacturing, marketing, distributing, warning, labeling studying, testing or selling the Prolift mesh, and;

j. Failing to use reasonable care in seeking and obtaining FDA clearance prior to marketing and selling the device for implantation into the human body.

94. Failed to conduct post-market vigilance, or surveillance, by:

a. Monitoring or acting on findings in the scientific and medical literature; and

b. Monitoring or investigating and evaluating reports in the FDA adverse event databases for their potential significance for defendants' Pelvic Mesh Products.

95. Failed to comply with manufacturer requirements of the Medical Device Reporting (MDR) Regulations, specifically:

a. Failed to report MDRs (Medical Device [adverse event] Reports); and

b. Failed to investigate reports of serious adverse events.

96. As a direct and proximate result of Defendants' negligence, Plaintiff has been injured, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment

of life, economic loss and damages including, but not limited to medical expenses, lost income, and other damages.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT II: STRICT LIABILITY – MANUFACTURING DEFECT

97. Paragraphs 1-96 of the Complaint are hereby incorporated by reference as if fully set forth herein.

98. The Prolift mesh implanted in Plaintiff was not reasonably safe for its intended use and was defective with respect to its manufacture, as described herein, in that Defendants deviated materially from their design and manufacturing specifications and/or such design and manufacture posed an unreasonable risk of harm to Plaintiff.

99. The Defendants' Prolift mesh is inherently dangerous and defective, unfit and unsafe for their intended and reasonably foreseeable uses, and does not meet or perform to the expectations of patients and their health care providers.

100. The Prolift mesh creates risks to the health and safety of the patients that are far more significant and devastating than the risks posed by other products and procedures available to treat the corresponding medical conditions, and which far outweigh the utility of the Prolift mesh.

101. Defendants have intentionally and recklessly manufactured the Prolift mesh with wanton and willful disregard for the rights and health of the Plaintiff, and with malice, placing their economic interests above the health and safety of the Plaintiff.

102. As a direct and proximate result of the Defendants' defective manufacture of the Prolift mesh, Plaintiff has been injured, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, economic loss and damages including, but not limited to medical expenses, lost income, and other damages.

103. The Defendants are strictly liable in tort to the Plaintiff for their wrongful conduct.

WHEREFORE, Plaintiff demands judgment against Defendants of compensatory damages, punitive damages, interest, attorneys' fees, costs of suit, and such further relief as the Court deems equitable and just.

COUNT III: STRICT LIABILITY – FAILURE TO WARN

104. Paragraphs 1-103 of the Complaint are hereby incorporated by reference as if fully set forth herein.

105. The Defendants failed to properly and adequately warn and instruct the Plaintiff and her health care providers as to the proper candidates, and the safest and most effective methods of implantation and use of the Defendants' Prolift mesh.

106. The Defendants failed to properly and adequately warn and instruct the Plaintiff and her health care providers as to the risks and benefits of the Defendants' Prolift mesh, given the Plaintiff's condition and need for information.

107. The Defendants failed to properly and adequately warn and instruct the Plaintiff and her health care providers with regard to the inadequate research and testing of the Prolift mesh, and the complete lack of a safe, effective procedure for removal of the Prolift mesh.

108. In addition, the Prolift mesh was defective due to the lack of necessary and appropriate warnings regarding, but not limited to, the following:

a. the Prolift mesh's propensities to contract, retract, and/or shrink inside the body;

b. the Prolift mesh's propensities for degradation, fragmentation, disintegration and/or creep;

c. the Prolift mesh's inelasticity preventing proper mating with the pelvic floor and vaginal region;

d. the rate and manner of mesh erosion or extrusion;

e. the risk of chronic inflammation resulting from the Prolift mesh;

f. the risk of chronic infections resulting from the Prolift mesh;

g. the risk of permanent vaginal or pelvic scarring as a result of the Prolift mesh;

h. the risk of recurrent, intractable pelvic pain and other pain resulting from the Prolift mesh;

i. the need for corrective or revision surgery to adjust or remove the Prolift mesh;

j. the severity of complications that could arise as a result of implantation of the Prolift mesh;

k. the hazards associated with the Prolift mesh;

l. the Prolift mesh's defects described herein;

m. treatment of pelvic organ prolapse and stress urinary incontinence with the Prolift mesh is no more effective than feasible available alternatives;

n. treatment of pelvic organ prolapse and stress urinary incontinence with the Prolift mesh exposes patients to greater risk than feasible available alternatives;

o. treatment of pelvic organ prolapse and stress urinary incontinence with the Prolift mesh makes future surgical repair more difficult than feasible available alternatives;

p. use of the Prolift mesh puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

q. removal of the Prolift mesh due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and

r. complete removal of the Prolift mesh may not be possible and may not result in complete resolution of the complications, including pain.

109. The Defendants intentionally, recklessly, and maliciously misrepresented the safety, risks, and benefits of the Defendants' Prolift mesh, understating the risks and exaggerating the benefits in order to advance their own financial interests, with wanton and willful disregard for the rights and health of the Plaintiff.

110. As a direct and proximate result of the Prolift mesh's aforementioned defects, Plaintiff has been injured, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, economic loss and damages including, but not limited to medical expenses, lost income, and other damages.

111. The Defendants are strictly liable in tort to the Plaintiff for their wrongful conduct.

WHEREFORE, Plaintiff demands judgment against Defendants of compensatory damages, punitive damages, interest, attorneys' fees, costs of suit, and such further relief as the Court deems equitable and just.

COUNT IV: STRICT LIABILITY – DEFECTIVE PRODUCT

112. Paragraphs 1-111 of the Complaint are hereby incorporated by reference as if fully set forth herein. At the time of Plaintiff's injuries, the Defendants' Prolift mesh was defective and unreasonably dangerous to foreseeable consumers, patients, and users, including Plaintiff, and the warnings labels, and instructions were deficient.

113. The Defendants' Prolift mesh is inherently dangerous and defective, unfit and unsafe for their intended and reasonably foreseeable uses, and does not meet or perform to the expectations of patients and their health care providers.

114. Plaintiff brings strict product liability claims under the common law, and *Section 402A of the Restatement of Torts (Second)*.

115. As a proximate result of the Defendants' design, manufacture, marketing, sale, and distribution of the Prolift mesh, Plaintiff has been injured, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, and economic damages.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT V: STRICT LIABILITY – DESIGN DEFECT

116. Plaintiff incorporates by reference paragraphs 1-115 of this Complaint as if fully set forth herein.

117. Prolift mesh implanted in Plaintiff was not reasonably safe for its intended use and was defective as described herein with respect to its design. As previously stated, the Prolift mesh' design defects include, but are not limited to:

a. the use of polypropylene material and/or collagen material in the Prolift mesh and the immune reaction that results from such material, causing adverse reactions and injuries;

b. the design of the Prolift mesh to be inserted into and through an area of the body with high levels of bacteria that adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

c. biomechanical issues with the design of the Prolift mesh, including, but not limited to, the propensity of the Prolift mesh to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

d. the use and design of arms and anchors in the Prolift mesh, which, when placed in the women, are likely to pass through contaminated spaces and injure major nerve routes in the pelvic region;

e. the propensity of the Prolift mesh for "creep," or to gradually elongate and deform when subject to prolonged tension inside the body;

f. the inelasticity of the Prolift mesh, causing them to be improperly mated to the delicate and sensitive areas of the pelvis where they are implanted, and causing pain upon normal daily activities that involve movement in the pelvis (e.g., intercourse, defecation);

g. the propensity of the Prolift mesh for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time;

h. the propensity of the Prolift mesh for particle loss or "shedding", which causes a chronic inflammatory response and fibrotic reaction, and results in continuing injury over time; the lack of porosity of the Prolift mesh, which leads to fibrotic bridging and results in continuing injury over time; and

i. the creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanting according to the manufacturers' instructions.

118. As a direct and proximate result of the Prolift mesh's aforementioned defects as described herein, Plaintiff experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo future medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

119. Defendants are strictly liable to Plaintiff for designing a defective product.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT VI: COMMON LAW FRAUD

120. Plaintiff incorporates by reference paragraphs 1-119 of this Complaint as if fully set forth herein.

121. Defendants falsely and fraudulently represented and continue to represent to the medical and healthcare community, Plaintiff, and the public that the Prolift mesh had been tested and was found to be safe and effective.

122. The representations made by Defendants were, in fact, false. When Defendants made their representations, Defendants knew and/or had reason to know that those representations were false, and Defendants willfully, wantonly, and recklessly disregarded the inaccuracies in their representations and the dangers and health risks to users of the Prolift mesh.

123. These representations were made by Defendants with the intent of defrauding and deceiving the medical community, Plaintiff, and the public, and also inducing the medical community, Plaintiff, and the public, to recommend, prescribe, dispense, and purchase the Prolift mesh for use as a means of treatment for stress urinary incontinence and/or prolapse, all of which evinced a callous, reckless, willful, and depraved indifference to the health, safety, and welfare of Plaintiff.

124. In representations to Plaintiff and/or to Plaintiff's healthcare providers, Defendants fraudulently concealed and intentionally or recklessly omitted the following material information:

a) That the Defendants' Prolift mesh was not as safe as other products and procedures available to treat incontinence and/or prolapse;

b) That the Defendants' Prolift mesh was more effective than other products and procedures available to treat incontinence and/or prolapse;

c) That the risk of adverse events with the Defendants' Prolift mesh was higher than with other products and procedures available to treat incontinence and/or prolapse;

d) The Defendants' Prolift mesh was not adequately tested;

e) That the limited clinical testing revealed the Defendants' Prolift mesh had a higher risk of adverse effects, in addition to, and above and beyond those associated with other products and procedures available to treat incontinence and/or prolapse;

f) That Defendants deliberately failed to follow up on the adverse results from clinical studies and formal and informal reports from physicians and other healthcare providers and buried and/or misrepresented those findings;

g) That Defendants deliberately chose to forego studies that might reveal the true rate of adverse events or otherwise necessitate the need to reveal information as to adverse events to the Plaintiff, the medical community, or the regulatory authorities;

h) That Defendants were aware of dangers in the Defendants' Prolift mesh in addition to and above and beyond those associated with other products and procedures available to treat incontinence and/or prolapse;

i) That the Defendants' Prolift mesh was defective, and that it caused dangerous and adverse side effects, including but not limited to higher incidence of erosion and failure, at a much more significant rate than other products and procedures available to treat incontinence and/or prolapse;

j) That patients needed to be monitored more regularly than usual while using the Defendants' Prolift mesh and that in the event the products needed to be removed that the procedures to remove them had a very high failure rate and/or needed to be performed repeatedly;

k) That the Defendants' Prolift mesh was manufactured negligently;

l) That the Defendants' Prolift mesh was manufactured defectively;

m) That the Defendants' Prolift mesh was designed negligently, and designed defectively; and

n) That the Defendants' had not sought nor obtained FDA clearance at the time it began marketing and selling the Prolift mesh.

125. Defendants were under a duty to disclose to Plaintiff and her physicians, the defective nature of the Defendants' Prolift mesh, including, but not limited to, the heightened risks of erosion, failure, and permanent injury.

126. Defendants had sole access to material facts concerning the defective nature of the products and their propensity to cause serious and dangerous side effects and hence, cause dangerous injuries and damage to persons who used the Defendants' Prolift mesh.

127. Defendants' concealment and omissions of material fact concerning the safety of the Prolift mesh were made purposefully, willfully, wantonly, and/or recklessly to mislead, to

cause Plaintiff's physicians and healthcare providers to purchase, prescribe, and/or dispense the Prolift mesh; and/or to mislead Plaintiff into reliance and cause Plaintiff to use the Defendants' Prolift mesh.

128. At the time these representations were made by Defendants, and at the time Plaintiff used the Prolift mesh, Plaintiff was unaware of the falsehood of these representations, and reasonably believed them to be true.

129. Defendants knew and had reason to know that the Defendants' Prolift mesh could and would cause severe and grievous personal injury to the users of the Defendants' Prolift mesh, and that it were inherently dangerous in a manner that exceeded any purported, inaccurate, or otherwise downplayed warnings.

130. In reliance upon these false representations, Plaintiff was induced to, and did use the Prolift mesh, thereby sustaining severe and permanent personal injuries and damages. Defendants knew or had reason to know that Plaintiff and her physicians and other healthcare providers had no way to determine the truth behind Defendants' concealment and omissions, and that these included material omissions of facts surrounding the use of the Defendants' Prolift mesh, as described in detail herein.

131. Plaintiff reasonably relied on revealed facts which foreseeably and purposefully suppressed and concealed facts that were critical to understanding the real dangers inherent in the use of the Defendants' Prolift mesh.

132. Having knowledge based upon Defendants' research and testing, or lack thereof, Defendants blatantly and intentionally distributed false information, including but not limited to assuring Plaintiff, the public, and Plaintiff's healthcare providers and physicians, that the Defendants' Prolift mesh was safe for use as a means of providing relief from stress urinary incontinence and/or prolapse and were as safe or safer than other products and/or procedures

available and on the market. As a result of Defendants' research and testing, or lack thereof, Defendants intentionally omitted, concealed and suppressed certain results of testing and research to healthcare professionals, Plaintiff, and the public at large.

133. Defendants had a duty when disseminating information to the public to disseminate truthful information; and a parallel duty not to deceive the public, Plaintiff, Plaintiff's healthcare providers, and the United States Food and Drug Administration ("FDA").

134. The information distributed to the public, the medical community, the FDA, and Plaintiff, by Defendants included, but was not limited to websites, information presented at medical and professional meetings, information disseminated by sales representatives to physicians and other medical care providers, reports, press releases, advertising campaigns, television commercials, print advertisements, billboards and other commercial media containing material representations, which were false and misleading, and contained omissions and concealment of the truth about the dangers of the use of the Defendants' Prolift mesh.

135. Defendants intentionally made material misrepresentations to the medical community and public, including Plaintiff, regarding the safety of the Defendants' Prolift mesh specifically that the Prolift mesh did not have dangerous and/or serious adverse health safety concerns, and that the Defendants' Prolift mesh was as safe or safer than other means of treating stress urinary incontinence and/or prolapse.

136. Defendants intentionally failed to inform the public, including Plaintiff, of the high failure rate including erosion, the difficulty or impossibility of removing the mesh, and the risk of permanent injury.

137. Defendants chose to over-promote the purported safety, efficacy and benefits of the Defendants' Prolift mesh instead.

138. Defendants' intent and purpose in making these misrepresentations was to deceive and defraud the public, the medical community, and Plaintiff; to gain the confidence of the public, the medical community, and Plaintiff; to falsely assure them of the quality and fitness for use of the Products; and induce Plaintiff, the public and the medical community to request, recommend, prescribe, dispense, purchase, and continue to use the Defendants' Prolift mesh.

139. Defendants made claims and representations in its documents submitted to the FDA and its reports to the public and to healthcare professionals and in advertisements that the Defendants' Prolift mesh had innovative beneficial properties and did not present serious health risks.

140. These representations, and others made by Defendants, were false when made and/or were made with the pretense of actual knowledge when such knowledge did not actually exist, and were made recklessly and without regard to the true facts.

141. These representations, and others made by Defendants, were made with the intention of deceiving and defrauding Plaintiff, Plaintiff's healthcare professionals and other members of the healthcare community, and were made in order to induce Plaintiff, and their respective healthcare professionals, to rely on misrepresentations, and caused Plaintiff to purchase, rely, use, and request the Defendants' Prolift mesh and their healthcare professionals to dispense, recommend, or prescribe the Defendants' Prolift mesh.

142. Defendants recklessly and/or intentionally falsely represented the dangerous and serious health and safety concerns inherent in the use of the Defendants' Prolift mesh to the public at large, for the purpose of influencing the sales of Prolift mesh known to be dangerous and defective, and/or not as safe as other alternatives.

143. Defendants willfully and intentionally failed to disclose the truth, failed to disclose material facts and made false representations, for the purpose of deceiving and lulling

Plaintiff, as well as her healthcare professionals, into a false sense of security, so that Plaintiff and her healthcare providers would rely on Defendants' representations, and Plaintiff would request and purchase the Defendants' Prolift mesh, and that their healthcare providers would dispense, prescribe, and recommend the Defendants' Prolift mesh.

144. Defendants utilized direct-to-consumer advertising to market, promote, and advertise the Defendants' Prolift mesh.

145. At the time the representations were made, Plaintiff and her healthcare providers did not know the truth about the dangers and serious health and/or safety risks inherent in the use of the Defendants' Prolift mesh. Plaintiff did not discover the true facts about the dangers and serious health and/or safety risks, nor did Plaintiff discover the false representations of Defendants, nor would Plaintiff with reasonable diligence have discovered the true facts or Defendant's misrepresentations.

146. Had the Plaintiff known the true facts about the dangers and serious health and/or safety risks of the Defendants' Prolift mesh, Plaintiff would not have purchased, used, or relied on Defendants' Prolift mesh.

147. Defendants' wrongful conduct constitutes fraud and deceit, and was committed and perpetrated willfully, wantonly, and/or purposefully on Plaintiff.

148. As a direct and proximate result of Defendants' conduct, Plaintiff experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo future medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages,

punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT VII: FRAUDULENT CONCEALMENT

149. Plaintiff incorporates by reference paragraphs 1-148 of this Complaint as if fully set forth herein.

150. Plaintiff brings this fraudulent concealment claim under the common law.

151. Throughout the relevant time period, Defendants knew that their Prolift mesh was defective and unreasonably unsafe for their intended purpose.

152. Defendants fraudulently concealed from and/or failed to disclose to or warn Plaintiff, her physicians and the medical community that their Prolift mesh was defective, unsafe, and unfit for the purposes intended, and that they were not of merchantable quality.

153. Defendants were under a duty to Plaintiff to disclose and warn of the defective nature of the Products because:

a) Defendants were in a superior position to know the true quality, safety and efficacy of the Defendants' Prolift mesh;

b) Defendants knowingly made false claims about the safety and quality of the Defendants' Prolift mesh in the documents and marketing materials Defendants provided to the FDA, physicians, and the general public; and

c) Defendants fraudulently and affirmatively concealed the defective nature of the Defendants' Prolift mesh from Plaintiff.

154. The facts concealed and/or not disclosed by Defendants to Plaintiff were material facts that a reasonable person would have considered to be important in deciding whether or not to purchase and/or use the Defendants' Prolift mesh.

155. Defendants intentionally concealed and/or failed to disclose the true defective nature of the Prolift mesh so that Plaintiff would request and purchase the Defendants' Prolift mesh, and that her healthcare providers would dispense, prescribe, and recommend the

Defendants' Prolift mesh, and Plaintiff justifiably acted or relied upon, to her detriment, the concealed and/or non-disclosed facts as evidenced by her purchase of the Defendants' Prolift mesh.

156. Defendants, by concealment or other action, intentionally prevented Plaintiff and Plaintiff's physicians and other healthcare providers from acquiring material information regarding the lack of safety and effectiveness of the Defendants' Prolift mesh, and are subject to the same liability to Plaintiff for Plaintiff's pecuniary losses, as though Defendants had stated the non-existence of such material information regarding the Defendants' Prolift mesh's lack of safety and effectiveness and dangers and defects, and as though Defendants had affirmatively stated the non-existence of such matters that Plaintiff was thus prevented from discovering the truth. Defendants therefore have liability for fraudulent concealment under all applicable law, including, *inter alia*, *Restatement (Second) of Torts* § 550 (1977).

157. As a proximate result of the Defendants' conduct, Plaintiff has been injured, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, and economic damages.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT VIII: CONSTRUCTIVE FRAUD

158. Plaintiff incorporates by reference paragraphs 1-157 of this Complaint as if fully set forth herein.

159. Defendants are in a unique position of knowledge concerning the quality, safety and efficacy of the Defendants' Prolift mesh, which knowledge is not possessed by Plaintiff or

her physicians, and Defendants thereby hold a position of superiority over Plaintiff and her physicians.

160. Despite their unique and superior knowledge regarding the defective nature of the Defendants' Prolift mesh, Defendants continue to suppress, conceal, omit, and/or misrepresent information to Plaintiff, the medical community, and/or the FDA, concerning the severity of risks and the dangers inherent in the intended use of the Defendants' Prolift mesh, as compared to other products and forms of treatment.

161. For example, scientists in the recent study published in *Obstetrics & Gynecology*, August, 2010, found that the complication rate was so high that the clinical trial was halted early.

162. Defendants have concealed and suppressed material information, including limited clinical testing, that would reveal that the Defendants' Prolift mesh had a higher risk of adverse effects, in addition to, and exceeding those associated with alternative procedures and available devices. Instead, Defendants have misrepresented the safety and efficacy of the Prolift mesh.

163. Upon information and belief, Defendants' misrepresentations are designed to induce physicians and Plaintiff to prescribe, dispense, recommend and/or purchase the Defendants' Prolift mesh. Plaintiff and the medical community have relied upon Defendants' representations.

164. Defendants took unconscionable advantage of their dominant position of knowledge with regard to Plaintiff and her medical providers and engaged in constructive fraud in their relationship with Plaintiff and her medical providers. Plaintiff reasonably relied on Defendants' representations.

165. As a proximate result of the Defendants' conduct, Plaintiff has been injured, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, and economic damages.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT IX: NEGLIGENT MISREPRESENTATION

166. Plaintiff incorporates by reference paragraphs 1-165 of this Complaint as if fully set forth herein. Defendants had a duty to accurately and truthfully represent to the medical and healthcare community, Plaintiff, and the public, that the Prolift mesh had not been adequately tested and found to be safe and effective for the treatment of incontinence and prolapse. The representations made by Defendants, in fact, were false.

167. Defendants failed to exercise ordinary care in the representations concerning the Prolift mesh while they were involved in their manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce, because Defendants negligently misrepresented the Prolift mesh's high risk of unreasonable, dangerous, adverse side effects.

168. Defendants breached their duty in representing that the Defendants' Prolift mesh has no serious side effects different from older generations of similar products and/or procedures to Plaintiff, Plaintiff's physicians, and the medical and healthcare community.

169. As a foreseeable, direct and proximate result of the negligent misrepresentation of Defendants as set forth herein, Defendants knew, and had reason to know, that the Prolift mesh had been insufficiently tested, or had not been tested at all, and that it lacked adequate and accurate warnings, and that it created a high risk, and/or higher than acceptable risk, and/or

higher than reported and represented risk, of adverse side effects, including, erosion, pain and suffering, surgery to remove the products, and other severe and personal injuries, which are permanent and lasting in nature.

170. As a direct and proximate result of the Defendants' conduct, Plaintiff has been injured, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, and economic damages.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT X: BREACH OF EXPRESS WARRANTY

171. Plaintiff incorporates by reference paragraphs 1-170 of this Complaint as if fully set forth herein.

172. At all relevant and material times, Defendants manufactured, distributed, advertised, promoted, and sold the Defendants' Prolift mesh.

173. At all relevant times, Defendants intended that the Defendants' Prolift mesh be used in the manner that Plaintiff in fact used them and Defendants expressly warranted that each product was safe and fit for use by consumers, that each product was of merchantable quality, that its side effects were minimal and comparable to other pelvic mesh products, and that it was adequately tested and fit for its intended use.

174. At all relevant times, Defendants were aware that consumers, including Plaintiff, would use the Prolift mesh; which is to say that Plaintiff was a foreseeable user of the Defendants' Prolift mesh.

175. Plaintiff and/or her implanting physicians were at all relevant times in privity with Defendants.

176. The Defendants' Prolift mesh was expected to reach and did in fact reach consumers, including Plaintiff and her implanting physicians, without substantial change in the condition in which it was manufactured and sold by Defendants.

177. Defendants breached various express warranties with respect to the Prolift mesh including the following particulars:

a) Defendants represented to Plaintiff and her physicians and healthcare providers through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the Defendants' Prolift mesh was safe and fraudulently withheld and concealed information about the substantial risks of serious injury and/or death associated with using the Prolift mesh;

b) Defendants represented to Plaintiff and her physicians and healthcare providers that the Defendants' Prolift mesh was as safe, and/or safer than other alternative procedures and devices, that complications are rare, and fraudulently concealed information, which demonstrated that the Prolift mesh was not safer than alternatives available on the market and that complications were not, in fact, rare; and

c) Defendants represented to Plaintiff and her physicians and healthcare providers that the Defendants' Prolift mesh was more efficacious than other alternative medications and fraudulently concealed information, regarding the true efficacy of the Prolift mesh.

178. In reliance upon Defendants' express warranties, Plaintiff was implanted with the Defendants' Prolift mesh as prescribed and directed, and therefore, in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants.

179. At the time of making such express warranties, Defendants knew or should have known that the Defendants' Prolift mesh does not conform to these express representations because the Defendants' Prolift mesh was not safe and had numerous serious side effects, many of which are common and Defendants did not accurately warn about, thus making the Defendants' Prolift mesh unreasonably unsafe for their intended purpose.

180. Members of the medical community, including physicians and other healthcare professionals, as well as Plaintiff and the Public relied upon the representations and warranties of Defendants in connection with the use recommendation, description, and/or dispensing of the Defendants' Prolift mesh.

181. Defendants breached their express warranties to Plaintiff in that the Defendants' Prolift mesh was not of merchantable quality, safe and fit for their intended uses, nor was it adequately tested.

182. Defendants' breaches constitute violations of common law principles and the statutory provisions.

183. As a direct and proximate result of the Defendants' conduct, Plaintiff has been injured, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, and economic damages.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT XI: BREACH OF IMPLIED WARRANTY

184. Plaintiff incorporates by reference paragraphs 1-183 of this Complaint as if fully set forth herein.

185. At all relevant and material times, Defendants manufactured, distributed, advertised, promoted, and sold the Defendants' Prolift mesh.

186. At all relevant times, Defendants intended that the Defendants' Prolift mesh be implanted for the purposes and in the manner those Plaintiff or Plaintiff's implanting physicians

in fact used they and Defendants impliedly warranted each Prolift mesh to be of merchantable quality, safe and fit for such use, even though it was not adequately tested.

187. Defendants were aware that consumers, including Plaintiff or Plaintiff's physicians, would implant the Defendants' Prolift mesh in the manner directed by the instructions for use; which is to say that Plaintiff was a foreseeable user of the Defendants' Prolift mesh.

188. Plaintiff and/or her physicians were at all relevant times in privity with Defendants.

189. The Defendants' Prolift mesh was expected to reach and did in fact reach consumers, including Plaintiff or Plaintiff's physicians, without substantial change in the condition in which it was manufactured and sold by Defendants.

190. Defendants breached various implied warranties with respect to the Defendants' Prolift mesh, including, but not limited to, the following particulars:

a) Defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the Defendants' Prolift mesh was safe and fraudulently withheld and concealed information about the substantial risks of serious injury and/or death associated with using the Prolift mesh;

b) Defendants represented that the Defendants' Prolift mesh was safe, and/or safer than other alternative devices or procedures and that complications were rare, and fraudulently concealed information, which demonstrated that the Defendants' Prolift mesh was not as safe or safer than alternatives available on the market; and

c) Defendants represented that the Defendants' Prolift mesh was more efficacious than alternative pelvic mesh products and procedures and fraudulently concealed information, regarding the true efficacy of the Defendants' Prolift mesh.

191. In reliance upon Defendants' implied warranty, Plaintiff used the Pelvic Mesh Products Prolift mesh as prescribed and in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants.

192. Defendants breached their implied warranty to Plaintiff in that the Defendants' Prolift mesh was not of merchantable quality, safe and fit for their intended use, or adequately tested, in violation of Common Law principles and the statutory provisions.

193. As a direct and proximate result of the Defendants' conduct, Plaintiff has been injured, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, and economic damages.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT XII: GROSS NEGLIGENCE

194. Plaintiff incorporates by reference paragraphs 1-193 of this Complaint as if fully set forth herein.

195. The wrongs done by Defendants were aggravated by the kind of malice, fraud, and grossly negligent disregard for the rights of others, the public, and Plaintiff for which the law would allow, and which Plaintiff will seek at the appropriate time under governing law for the imposition of exemplary damages, in that Defendants' conduct, including the failure to comply with applicable Federal standards: was specifically intended to cause substantial injury to Plaintiff; or when viewed objectively from Defendants' standpoint at the time of the conduct, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and Defendants were actually, subjectively aware of the risk involved, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others; or included a material representation that was false, with Defendants, knowing that it was false or

with reckless disregard as to its truth and as a positive assertion, with the intent that the representation is acted on by Plaintiff.

196. Plaintiff relied on the representation and suffered injury as a proximate result of this reliance.

197. Plaintiff therefore will seek to assert claims for exemplary damages at the appropriate time under governing law in an amount within the jurisdictional limits of the Court.

198. Plaintiff also alleges that the acts and omissions of named Defendants, whether taken singularly or in combination with others, constitute gross negligence that proximately caused the injuries to Plaintiff. In that regard, Plaintiff will seek exemplary damages in an amount that would punish Defendants for their conduct and which would deter other manufacturers from engaging in such misconduct in the future.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT XIII: PUNITIVE DAMAGES

199. Plaintiff incorporates by reference paragraphs 1-198 of this First Amended Master Complaint as if fully set forth herein.

200. Defendants sold their Prolift mesh to Plaintiff's healthcare providers and other healthcare providers throughout the United States without doing adequate testing to ensure that the Products were reasonably safe for implantation in the female pelvic area.

201. Defendants sold the Prolift mesh to Plaintiff's health care providers and other health care providers throughout the United States in spite of their knowledge that their Prolift mesh can shrink, disintegrate and/or degrade inside the body, and cause the other problems

heretofore set forth in this Complaint, thereby causing severe and debilitating injuries suffered by the Plaintiff.

202. At all times relevant hereto, Defendants knew or should have known that the Defendants' Prolift mesh was inherently dangerous with respect to the risks of erosion, failure, pain and suffering, loss of life's enjoyment, remedial surgeries and treatments in an effort to cure the conditions proximately related to the use of the product, as well as other severe and personal injuries which are permanent and lasting in nature.

203. At all times material hereto, Defendants attempted to misrepresent and did misrepresent facts concerning the safety of the Defendants' Prolift mesh.

204. Defendants' misrepresentations included knowingly withholding material information from the medical community and the public, including Plaintiff, concerning the safety and efficacy of the Defendants' Prolift mesh.

205. At all times material hereto, Defendants knew and intentionally and/or recklessly disregarded the fact that the Defendants' Prolift mesh causes debilitating and potentially lethal side effects with greater frequency than safer alternative methods products and/or procedures and/or treatment.

206. At all times material hereto, Defendants knew and intentionally and/or recklessly disregarded the fact that the Defendants' Prolift mesh causes debilitating and potentially lethal side effects with greater frequency than safer alternative products and/or methods of treatment and recklessly failed to advise healthcare providers, the public and the FDA of same.

207. At all times material hereto, Defendants intentionally misstated and misrepresented data and continue to misrepresent data so as to minimize the true and accurate risk of injuries and complications caused by the Defendants' Prolift mesh.

208. Notwithstanding the foregoing, Defendants continue to aggressively market the Defendants' Prolift mesh to consumers, including Plaintiff, without disclosing the true risk of side effects and complications.

209. Defendants knew of the Defendants' Prolift mesh defective and unreasonably dangerous nature, but continued to manufacture, produce, assemble, market, distribute, and sell the Defendants' Prolift mesh so as to maximize sales and profits at the expense of the health and safety of the Plaintiff, in conscious and/or reckless disregard of the foreseeable harm caused by the Defendants' Prolift mesh.

210. Defendants continue to intentionally conceal and/or recklessly and/or grossly negligently fail to disclose to the public, including Plaintiff, the serious side effects of the Defendants' Prolift mesh in order to ensure continued and increased sales.

211. Defendants' intentionally, reckless and/or grossly negligent failure to disclose information deprived Plaintiff of necessary information to enable her to weigh the true risks of using the Defendants' Prolift mesh against their benefits.

212. As a direct and proximate result of the foregoing acts and omissions, Plaintiff has required and will require health care and services, and have incurred medical, health care, incidental, and related expenses. Plaintiff is informed and believe and further allege that Plaintiff will in the future be required to obtain further medical care and/or hospital care and medical services.

213. Defendants have engaged in conduct entitling Plaintiff to an award of punitive damages pursuant Common Law principles and the statutory provisions.

214. Defendants' conduct as described herein shows willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care which raises the presumption of conscious indifference to consequences, thereby justifying an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, together with interest, costs of suit, attorneys' fees, punitive damages, and such further relief as the Court deems equitable and just.

VII. JURY DEMAND

215. Plaintiff requests a jury trial and have tendered the required fee.

VIII. PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly and severally and requests compensatory damages, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper as well as:

1. Compensatory damages to Plaintiff for past, present, and future damages, including, but not limited to, pain and suffering for severe and permanent personal injuries sustained by Plaintiff, health and medical care costs, together with interest and costs as provided by law;

2. The costs of these proceedings;

3. All ascertainable economic damages;

4. Punitive damages;

5. Such other and further relief as this Court deems just and proper.

Respectfully submitted,

HOUSSIERE, DURANT & HOUSSIERE, LLP

By: */s/Randal Kauffman-*

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